

REMARKS

This is in response to the Office Action dated August 24, 2004, and the references cited therewith.

Claims 1, 9, 22, 23, 28, 38, 39, 42-43, 45, 50 and 57 are amended, no claims are canceled or added; as a result, claims 1-57 are now pending in this application.

§102 Rejection of the Claims

Claims 9, 16, 22, 23, 28 and 33 were rejected under 35 USC § 102(b) as being anticipated by Bakels et al. (U.S. Patent No. 5,800,497), hereinafter Bakels.

Claims 9, 16, 22 and 23

Applicant respectfully traverses the rejections of claims 9, 16, 22 and 23. Applicant respectfully submits the cited reference fails to anticipate claims 9 and 23 because all of the elements are not identically shown. Applicant cannot find, for example, the at least one assembly including a rheometric material, the rheometric material contracts and/or stiffens when electrical current is applied thereto, as recited in claims 9 and 23. Claims 16 and 22 depend from claim 9 and thereby include all of its limitations. Applicant respectfully submits Bakels states at column 3, lines 21-25, “the electrode portion of the lead body features one or more cavities containing MRF fluid. Thus, when the MRF is *made solid through the presence of a magnetic field*, the corresponding section of the lead body will become stiffer.” (Emphasis Added). Applicant submits Bakels appears to solidify the MRF in the presence of a magnetic field and not with an assembly including a rheometrical material that contracts and/or stiffens when electrical current is applied thereto, as recited in claims 9 and 23 and incorporated in claims 16 and 22.

Reconsideration and allowance of claims 9, 16, 22 and 23 are respectfully requested.

Claim 28

Applicant respectfully traverses the rejection of claim 28. Applicant respectfully submits the cited reference fails to anticipate claim 28 because all of the elements are not identically shown. Applicant cannot find, for example, means for electrically stiffening the at least one assembly and the device body, wherein electrical current is applied to the at least one assembly,

as recited in claim 28. Applicant respectfully submits Bakels states at column 3, lines 21-25, “the electrode portion of the lead body features one or more cavities containing MRF fluid. thus, when the MRF is *made solid through the presence of a magnetic field*, the corresponding section of the lead body will become stiffer.” (Emphasis Added). Applicant submits Bakels appears to solidify the MRF in the presence of a magnetic field and not with means for electrically stiffening the at least one assembly and the device body, where electrical current is applied to the at least one assembly, as recited in claim 28.

Moreover, Applicant traverses the rejection of claim 28 because the Office Action appears to disregard the structure disclosed in the specification corresponding to the means for electrically stiffening the at least one assembly and the device body, wherein electrical current is applied to the at least one assembly, as recited in claim 28. Claim 28 is a means-plus-function claim under 35 U.S.C. § 112, paragraph 6. M.P.E.P. § 2183 requires the Office Action to make a *prima facie* case of equivalence under 35 U.S.C. 112, paragraph 6. However, Applicant cannot find an explanation or a rationale as to why the disclosure of Bakels is equivalent to the corresponding elements disclosed in the specification as required by M.P.E.P. § 2183. Applicant respectfully submits that Bakels does not disclose an equivalent to the corresponding elements disclosed in the specification under 35 U.S.C. 112, paragraph 6. Applicant submits Bakels fails to anticipate claim 28, and therefore claim 28 is in condition for allowance.

Reconsideration and allowance of claim 28 are respectfully requested.

Claims 1, 3-6, 8-10, 12-14, 16, 21-23, 26, 28, 29, 33, 38, 39, 41-43, 45-48, 50, 51 and 57 were rejected under 35 USC § 102(e) as being anticipated by Maseda (U.S. Patent No. 6,514,237).

Claims 1, 3-6, 8-10, 12-14, 16, 21-23, 26, 28, 29 and 33

Applicant respectfully traverses the rejections of claims 1, 3-6, 8-10, 12-14, 16, 21-23, 26, 28, 29 and 33. Applicant respectfully submits the cited reference fails to anticipate claims 1, 3-6, 8-10, 12-14, 16, 21-23, 26, 28, 29 and 33 because all of the elements are not identically shown. Applicant cannot find, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and

from tissue, as recited in claims 1, 9, 23 and 28. Claims 3-6, 8; 10, 12-14, 16, 21, 22; 26; 29 and 33 depend from claims 1, 9, 23 and 28 respectively and thereby include all of their limitations.

Additionally, Applicant traverses the Office Action statement at page 3, section 4, “the examiner considers the conductive platinum metal discussed in col. 5, lines 1-19 to constitute at least one electrode with the electroactive polymer representing the rheometric material electrically coupled to the electrode. Platinum is considered to be capable of transmitting and receiving electrical signals to and from tissue due to its conductive and biocompatible nature.” According to M.P.E.P. § 2131, “the identical invention must be shown in as complete detail as is contained in the claim.” *See also In re Bond*, 910 F.2d 831 (Fed. Cir. 1990). Applicant submits Maseda does not appear to identically teach and/or show in as complete detail the use of at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claims 1, 9, 23 and 28 and incorporated in claims 3-6, 8, 10, 12-14, 16, 21, 22, 26, 29 and 33. Therefore, Applicant respectfully submits Maseda does not anticipate claims 1, 3-6, 8-10, 12-14, 16, 21-23, 26, 28, 29 and 33.

Reconsideration and allowance of claims 1, 3-6, 8-10, 12-14, 16, 21-23, 26, 28, 29 and 33 are respectfully requested.

Claims 38, 39, 41-43, 45-48, 50, 51 and 57

Applicant respectfully traverses the rejections of claims 38, 39, 41-43, 45-48, 50, 51 and 57. Applicant respectfully submits the cited reference fails to anticipate claims 38, 39, 41-43, 45-48, 50, 51 and 57 because all of the elements are not identically shown. Applicant cannot find, for example, advancing at least a distal end of the device body to a first location within a body; and passing at least one instrument through an instrument lumen within the device body after advancing at least the distal end of the device body to the first location, wherein at least a portion of the at least one instrument is guided toward the first location within the body, as recited in claims 38 and 50. Claims 39, 41-43, 45-48; 50, 51 and 57 depend from claims 38 and 50 respectively and thereby include all of their limitations.

Reconsideration and allowance of claims 38, 39, 41-43, 45-48, 50, 51 and 57 are respectively requested.

§102/103 Rejection of the Claims

Claims 1, 5, 7, 38, 42, 43 and 45-48 were rejected under 35 USC § 102(b) as anticipated by, or in the alternative, under 25 USC § 103(a) as obvious over Bakels et al. (U.S. Patent No. 5,800,497).

1. The Office Action Fails to Provide a Case of Anticipation Because Bakels Does Not Identically Teach Each Element of the Claims Under Consideration.

Applicant respectfully traverses the rejections of claims 1, 5, 7, 38, 42, 43 and 45-48. Applicant respectfully submits the cited reference fails to anticipate claims 1 and 38 because all of the elements are not identically shown. Applicant cannot find, for example, a rheometric material electrically coupled with the at least one electrode, the rheometric material contracts and/or stiffens when electrical current is applied thereto, as recited in claim 1. Claims 5 and 7 depend from claim 1 and thereby include all of its limitations. Additionally, Applicant cannot find the rheometric material stiffening at least a portion of the device body when electrical energy is applied thereto, as recited in claim 38. Further, Applicant can not find, advancing at least a distal end of the device body to a first location within a body; and passing at least one instrument through an instrument lumen within the device body after advancing at least the distal end of the device body to the first location, wherein at least a portion of the at least one instrument is guided toward the first location within the body, as recited in claim 38. Claims 42, 43 and 45-48 depend from claim 38 and thereby include all of its limitations.

2. The Office Action Fails to Provide a *Prima Facie* Case of Obviousness Because the Proposed Modification of Bakels Does Not Teach or Suggest All the Elements of the Claims Under Consideration.

Moreover, Applicant respectfully submits the proposed modification of Bakels fails teach or suggest all the elements of claims 1, 5, 7, 38, 42, 43 and 45-48. Applicant can not find in the cited reference, for example, a rheometric material electrically coupled with the at least one electrode, the rheometric material contracts and/or stiffens when electrical current is applied thereto, as recited in claim 1. Claims 5 and 7 depend from claim 1 and thereby include all of its

limitations. Additionally, Applicant cannot find the rheometric material stiffening at least a portion of the device body when electrical energy is applied thereto, as recited in claim 38.

Claims 42, 43 and 45-48 depend from claim 38 and thereby include all of its limitations.

Moreover, Applicant cannot find, electrically coupling a rheometric material with the at least one electrode, wherein the at least one assembly includes the rheometric material, as recited in claim 38 and incorporated in claims 42, 43 and 45-48. Further, Applicant can not find, advancing at least a distal end of the device body to a first location within a body; and passing at least one instrument through an instrument lumen within the device body after advancing at least the distal end of the device body to the first location, wherein at least a portion of the at least one instrument is guided toward the first location within the body, as recited in claim 38.

Further, Applicant traverses the Office Action statement at page 5, section 6, “given that all the other leads disclosed by Bakels et al. comprise distal electrodes and given the showing of a conductor coil 101 abutting the cap 105, those of ordinary skill in the art would have recognized the cap to equate to an electrode, with the rheometric material electrically coupled by contact and contained therein.” Pursuant to M.P.E.P. § 707.07(g), “Where a major technical rejection is proper, it should be stated with a full development of reasons rather than by a mere conclusion.” The Office Action appears to merely conclude the cap 105 is an electrode without making a *prima facie* case of obviousness to support such an assertion. For example, the Office Action does not show any objective suggestion to modify Bakels in the manner proposed. Applicant respectfully requests a fully developed rejection to support this assertion or withdrawal of this line of argument.

3. The Office Action Fails to Provide a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Selectively Modify Bakels.

Further, the Office Action does not identify a proper motivation to modify Bakels.

According to M.P.E.P. § 2143.01, the mere fact that references *can* be modified does not render the resultant modification obvious unless prior art also suggests (i.e. a prior art supported objective suggestion) the desirability of modification. The Office Action states at page 5, section 6, “Given that all the other leads disclosed by Bakels et al. comprise distal electrodes and given the showing of a conductor coil 101 abutting the cap 105, those of ordinary skill in the art would

have recognized the cap to equate to an electrode, with the rheometric material electrically coupled by contact and contained therein.” However, no objective support is provided for such a conclusion. Moreover, the Office Action does not state how Bakels would be in need of, for example, a rheometric material electrically coupled with the at least one electrode, the rheometric material contracts and/or stiffens when electrical current is applied thereto, as recited in claim 1. Additionally, the Office Action does not state how Bakels would be in need of the rheometric material stiffening at least a portion of the device body when electrical energy is applied thereto, as recited in claim 38. Applicant cannot find any objective suggestion in Bakels to employ such structure or steps. In light of the lack of objective support, Applicant respectfully submits these statements do not appear to provide a motivation to selectively modify Bakels as required by M.P.E.P. § 2143.01.

4. The Office Action Fails to Establish a *Prima Facie* Case of Obviousness Because Bakels Teaches Away From the Claims.

Further still, according to M.P.E.P. § 2143.03, “Prior art must be considered in its entirety, including disclosures that teach away from the claims.” Prior art that teaches away from the claimed combination is a factor cutting against a finding of motivation to combine or modify the prior art. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path the applicant took. *In re Gurley*, 27 F.3d 551, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994); *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (C.C.P.A. 1969); *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 243, 245 (C.C.P.A. 1963).

Applicant submits, Bakels states at column 3, lines 21-25, “the electrode portion of the lead body features one or more cavities containing MRF fluid. Thus, when the MRF is *made solid through the presence of a magnetic field*, the corresponding section of the lead body will become stiffer.” (Emphasis Added). Bakels teaches away from the proposed modification or combination because Bakels advises using an MRF fluid that is made solid through a magnetic field as opposed to a rheometric material electrically coupled with the at least one electrode, where the rheometric material contracts and/or stiffens when electrical current is applied thereto, as recited

in claim 1. Additionally, Bakels teaches away from the proposed modification because Bakels advises solidifying the MRF fluid with a magnetic field as opposed to the rheometric material stiffening at least a portion of the device body when electrical energy is applied thereto, as recited in claim 38.

5. The Office Action Fails to Establish a *Prima Facie* Case of Obviousness Because the Office Action Does not Consider the Claims as a Whole.

Additionally, Applicant respectfully submits Office Action does not consider the claims as a whole according to MPEP § 2141.02. The Office Action states at page 5, section 6, “the examiner takes Official Notice that the use of cap electrodes on the distal ends of medical electrical leads is old and well-known by those of ordinary skill in the art. To employ a conductive electrode cap would have therefore been considered a matter of obvious design dependent upon the particular application of use.” In contrast, claim 1 recites that the medical device includes, *in combination with all of the elements of claim 1*, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue. Additionally, claim 38 recites that the method includes, *in combination with all of the elements of claim 38*, electrically coupling a rheometric material with the at least one electrode, wherein the at least one assembly includes the rheometric material. The Office Action fails to show teaching or suggestion for this new combination. Applicant respectfully submits the Office Action merely states the differences of the claims with respect to the prior art are obvious instead of focusing on the claims as a whole. Because the rejection focuses upon the differences of the claims and not the claims as a whole, a proper *prima facie* case of obviousness has not been established.

Reconsideration and allowance of claims 1, 5, 7, 38, 42, 43 and 45-48 are respectfully requested.

§103 Rejection of the Claims

Claim 41 was rejected under 35 USC § 103(a) as being unpatentable over Bakels et al. (U.S. Patent No. 5,800,497).

Applicant respectfully traverses the rejection of claim 41 because the proposed modification of Bakels does not teach or suggest all the elements of claim 41. Applicant can not find in the cited reference, for example, applying electrical energy includes selectively applying energy to each assembly at different times, as recited in claim 41.

Furthermore, Applicant respectfully submits claim 41 is patentable at least as a dependent claim of base claim 38, and the discussion for claim 38 above is repeated in support of claim 41.

Reconsideration and allowance of claim 41 are respectfully requested.

Response to Election/Restriction Arguments

According to the Office Action at page 2, section 1, “the applicants’ assertion that claims 1, 23 and 28 are generic is not agreed with. A generic claim must be generic to all species.” It appears the Examiner has identified species for the determination of generic claims. Applicant respectfully requests the Examiner submit a listing of the identified species in the next Office Action so Applicant may determine generic claims. Alternatively, Applicant submits the listing of generic claims provided in the response dated May 14, 2004 are generic to the single species described in the response. Further, Applicant continues to reserve the right to traverse the Restriction Requirement.

Reservation of the Right to Swear Behind

Applicant reserves the right to swear behind any references which are cited in a rejection under 35 U.S.C. §§102(a), 102(e), 103/102(a), and 103/102(e). Statements distinguishing the claimed subject matter over the cited documents are not to be interpreted as admissions that the documents used as references are prior art.

Documents Cited But Not Relied Upon in this Office Action

Applicant has reviewed the references made of record and not relied upon, but does not find them to be any more relevant than the patents discussed in the Office Action. Because the references are not made part of the rejections of this Office Action, Applicant need not address the additional reference. Applicant reserves the right to further address any rejections therefrom.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 371-2117 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23 day of November, 2004.

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